In the United States District Court
For the Western District of Texas
Waco Division

Gregory Scott Johnson	§	
	§	
	§	**CIVIL ACTION NO.**
v.	§	**W-09-CV-107**
	§	
Arkema, Inc.	§	

DEFENDANT ARKEMA INC.'S MOTION FOR SUMMARY JUDGMENT

TO THE HONORABLE JUDGE OF THE DISTRICT COURT:

COMES NOW, ARKEMA Inc. ("Arkema"), who is the Defendant herein, and files its Motion for Summary Judgment, and, in support of the Motion, states as follows:

INTRODUCTION

This is a "toxic tort" case. Plaintiff, Gregory Scott Johnson, alleges that he was injured while working at the Owens-Illinois glass bottle manufacturing plant in Waco, when he inhaled chemicals that escaped from equipment supplied by Arkema. Specifically, Plaintiff claims that he suffers from a restrictive lung disease as a result of inhaling monobutyltin trichloride ("MBTC") and/or hydrochloric acid ("HCl"). Discovery is complete, and the undisputed facts, as well as the admissions by Plaintiff's experts, establish that Arkema is entitled to summary judgment.

First, Arkema is entitled to summary judgment because there is no scientifically reliable evidence establishing that exposure to MBTC or HCl causes restrictive lung disease. There are no epidemiological studies linking the chemicals and the illness; indeed, there is no human study of any kind suggesting a link. There is no statistically significant evidence that inhaling either or both of the chemicals causes a lung restriction. Plaintiff's experts conceded there is no data that suggests inhaling MBTC or HCl increases the risk of suffering a restrictive lung disease. Indeed,

while individual case reports are not considered reliable evidence of causation, ***there is not even one reported case of any person contracting Plaintiff's alleged disease from inhaling MBTC and/or HCl.*** Despite an exhaustive search, Plaintiff has failed to identify even one piece of scientifically reliable evidence of causation that would pass muster under Texas law.

In the absence of any scientifically reliable evidence, Plaintiff's experts have attempted to stitch together a causation theory based on gross generalizations. Thus, Plaintiff's experts claim that MBTC and HCl are among a "class" of chemicals which can cause respiratory irritation, and that depending on highly individualized and poorly understood responses, irritation ***can*** lead to lung restriction. Not only are these theories lacking in scientifically reliable support (there are not even any epidemiological studies relating this chemical *class* to Plaintiff's disease), but Texas courts have specifically rejected attempts to prove causation in toxic tort cases by reference to a "class" of chemicals. Moreover, Texas law is clear that conclusions that a certain chemical ***can*** cause an illness fail to meet Plaintiff's burden of proving with reasonable probability that the chemical ***does*** cause the illness. Without any scientifically reliable evidence of causation, Plaintiff's tort claims fail under the well-established principles set forth in *Merrell Dow Pharms., Inc. v. Havner,* 953 S.W.2d. 706 (Tex. 1997).

Second, Arkema is entitled to summary judgment because Plaintiff's proffered causation and medical expert testimony is inadmissible under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Arkema has filed separate motions to exclude those experts, and incorporates those arguments herein by reference.

FACTUAL BACKGROUND

I. Plaintiff's Claims In This Case

Plaintiff works at a plant in Waco where Owens-Illinois ("Owens") produces glass bottles. During the manufacturing process, newly formed glass bottles, which have surface temperatures of several hundred degrees, pass under C-4 Hoods made by Arkema. In the C-4 Hoods, the bottles are sprayed with Arkema's Certincoat TC-100, a chemical comprised primarily of MBTC.[1] The Certincoat is used to strengthen and improve the bottles.

Johnson has been employed as a mechanic at the Owens plant for twelve years.[2] He claims that, on two separate occasions, he was exposed to chemical vapors escaping from a C-4 Hood. The first alleged exposure occurred in early June, 2007, when Johnson was called on to work close to the opening of a C-4 Hood.[3] He claims that, within fifteen minutes after he began to work in the area, his eyes were burning and watery and he had a sore throat, but he continued to work in the area continuously for the next four or five hours.[4] Johnson did not report this alleged exposure to Owens or to his family doctor, whom he saw a few days later.[5] After an examination and chest x-ray, Johnson's family doctor diagnosed him with pneumonia.[6] Johnson returned to work a few days later.[7]

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1 Under the elevated temperatures of the C-4 Hoods, MBTC vaporizes; MBTC then decomposes upon contact with the glass bottles and the hood itself. One of the decomposition products of MBTC is HCl.

2 October 1, 2009 Deposition Transcript of Gregory Scott Johnson, relevant excerpts of which are attached as Exhibit A, at 12.

3 Second Amended Complaint at ¶ 7.

4 Ex. A at 92.

5 Ex. A at 88-89, 91-94, 97.

6 Ex. A at 89-91, 94; Initial Expert Report of Charles J. Grodzin, M.D., a copy of which is attached as Exhibit B, at 3; Charles J. Grodzin, M.D. Deposition Exhibit ("Grodzin Dep. Ex.") 9, a copy of which is attached as Exhibit C.

7 Scott & White June 18, 2007 Clinic Notes, a copy of which is attached as Exhibit D.

Johnson claims that he was exposed to Certincoat vapors a second time on July 15, 2007, while working in the vicinity of a C-4 Hood.[8] Johnson alleges that, once again, within the first ten to fifteen minutes, his eyes and throat began to burn, his eyes were watery, he was coughing and wheezing, and he experienced shortness of breath and chest pain.[9] Despite these symptoms, Johnson claims that he continued to work in the area for the next two to three hours.[10] Johnson ultimately told his supervisor that he believed he had been injured by a chemical and, later that night, went to the emergency room.[11]

While at the emergency room, Johnson's objective lung function diagnostic tests - room air oximetry, exam and chest x-ray - were normal.[12] The chest x-ray showed that Johnson's lungs were clear and contained no evidence of active chest disease.[13] Based upon his statements, Johnson was diagnosed with an inhalation injury, given two nebulizer breathing treatments, and discharged.[14]

These are the only two exposures alleged by Johnson.[15] Since 2007, Johnson has continued to work at the Waco plant full-time.[16] In 2009, Johnson was promoted, and continues to perform his old maintenance job, but with increased supervisory responsibilities.[17] Johnson continues to work in the area where glass bottles are manufactured, and the C-4 Hoods continue

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8 Second Amended Complaint at ¶ 8.
9 Ex. A at 71-75.
10 Ex. A at 70-71.
11 Ex. A at 54-55.
12 June 3, 2010 Report of Robert Aris, M.D., a copy of which is attached as Exhibit E, at 2.
13 A copy of the July 16, 2007 x-ray report is attached as Exhibit F.
14 Ex. A at 101; Ex. E at 2.
15 Deposition Transcript of Charles J. Grodzin, M.D., relevant excerpts of which are attached as Exhibit G, at 63.
16 Ex. A at 119-20; August 25, 2010 Deposition Transcript of Gregory Scott Johnson, relevant excerpts of which are attached as Exhibit H, at 10-11.
17 Ex. H at 8-9.

in use.[18] Since 2007, the dates of his two alleged exposures, Johnson has worked more hours than ever before, and his income has increased.[19]

II. Plaintiff's Proffered Causation Evidence

Plaintiff has offered two witnesses who have opined regarding causation: Richard Schlesinger, Ph.D., a toxicologist who holds a teaching position at Pace University in New York, and Charles Grodzin, M.D., a medical doctor who practices at a clinic in Denton, Texas.[20] For the purposes of this Motion, Arkema does not challenge Dr. Schlesinger's qualifications as a toxicologist nor his bias. It is worth noting, however, that prior to beginning his work in this case, Dr. Schlesinger reviewed two articles regarding the burden of proof in toxic tort cases under Texas law that were sent to him by Plaintiff's counsel.[21]

A. Dr. Schlesinger's Proffered Opinions

Dr. Schlesinger's opinions are set forth in a report dated March 25, 2010.[22] Significantly, Dr. Schlesinger did not opine that inhalation of MBTC and/or HCl is a known reasonably likely cause of a restrictive lung disease. Nor did he give an opinion regarding the relative risk of developing a restrictive lung disease after inhaling MBTC and/or HCl. Instead, Dr. Schlesinger carefully couched his conclusions in general terms. The substance of his opinion is that inhaling respiratory irritants, the class of chemicals that includes MBTC and HCl, causes inflammation in the lungs, and this inflammation "can" progress to a restrictive lung disease depending on the individual response.[23]

Dr. Schlesinger's pertinent conclusions are as follows:

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18 Ex. A at 21.

19 Ex. H at 51.

20 Ex. G at 8-9; Preliminary Report of Expert Opinion of Richard B. Schlesinger, Ph.D., a copy of which is attached as Exhibit I, at 1; Deposition Transcript of Richard B. Schlesinger, Ph.D., relevant excerpts of which are attached as Exhibit J, at 12-13.

21 Ex. J at 61-62, 259-262.

22 Ex. I at 11.

23 Ex. I at 4, 10.

- MBTC and HCl are among the "class of chemicals known as strong irritants."[24]

- "The respiratory tract and ocular symptoms reported by Johnson are consistent with exposure to strong irritants."[25] Dr. Schlesinger later admitted, however, that Johnson could have displayed an irritant response due to some other agent in the plant.[26]

- The "pathophysiological response to irritant exposure is inflammation."[27] In the respiratory tract, inflammation can lead to a wide range of pathology, which ultimately is either resolved with no injury, or can progress to a restrictive lung disease.[28]

- Thus, inhalation of strong irritants ***"can also be associated"*** with later sequalae which result in significant respiratory impairment.[29] But, there is wide "inter-individual variability in response" to inflammation.[30] Dr. Schlesinger later admitted that the "factors which determine whether an initial respiratory injury progresses to chronic disease are not well defined," and that how chronic disease may or may not occur after inflammation "is one of the open questions in toxicology."[31]

- "Acute exposure to inhaled irritants has been shown to result in development of chronic lung disease, including restrictive lung disease, [and] exposure to MBTC and HCl has been implicated in development of chronic respiratory tract pathology."[32]

- Restrictive lung disease is "consistent with the known chronic effects of acute exposure to strong respiratory irritants, ***the chemical toxicological class*** which includes MBTC and HCl."[33]

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24 Ex. I at 4.
25 Ex. I at 10.
26 Ex. J at 109.
27 Ex. I at 4.
28 Ex. I at 4.
29 Ex. I at 10 (emphasis added).
30 Ex. I at 7.
31 Ex. J at 178-182.
32 Ex. I at 10.

- Johnson was exposed on two occasions to a chemical mixture containing vapors of MBTC and HCl.[34] Dr. Schlesinger based this opinion on information that he received from Plaintiff's counsel; he took no steps to confirm the exposure personally.[35] He admitted that he does not know what other respiratory irritants may have been present in the air at the plant when Johnson claims he was exposed.[36]

- Johnson "likely" was exposed to "peak" concentrations of between 10-50 mg/m^3 of MBTC and between 15-75 mg/m^3 (or 10-50 ppm) of HCl.[37] Schlesinger based this conclusion solely on an opinion proffered by another of Johnson's proposed expert witnesses, Jerry Lauderdale.[38] Dr. Schlesinger did not try to determine the average concentrations to which Johnson was exposed or the duration of his peak exposure.[39] Indeed, he conceded that, for all he knows, Johnson's "peak" exposure could have been at the low end of these ranges (*i.e.,* 10 ppm of HCl), and only for a minute or two.[40]

- The likely "peak" concentrations of Johnson's exposure are "above various guidelines aimed at protecting individuals from severe and irreversible respiratory tract damage."[41]

- Tissue damage from one exposure can "modulate," *i.e.,* exacerbate, effects from a subsequent exposure.[42] Dr. Schlesinger later admitted, however, that he does not know whether this actually occurred here.[43]

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33 Ex. I at 10 (emphasis added).
34 Ex. I at 3; Ex. J at 75.
35 Ex. J at 67-68.
36 Ex. J at 67-68. Dr. Schlesinger also did not know how close Johnson was to the chemical coating hood or whether Johnson was moving in and out of the area near the hood. *Id.* at 55-56.
37 Ex. I at 3.
38 Ex. J at 90. Dr. Schlesinger testified that that a peak concentration "would be the highest concentration that he was exposed to, as opposed to an average concentration over, say, an eight-hour period." Ex. J at 88.
39 Ex. J at 99-100.
40 Ex. J at 101.
41 Ex. I at 10.

Dr. Schlesinger further opined that, because Johnson was exposed to a mixture of chemicals, there was an "additivity" of dosage, in which "adverse biological effects from such an exposure ***may result*** even when the concentration of each alone is below some effect threshold."[44]

B. Dr. Grodzin's Proffered Opinions

Dr. Grodzin is not a toxicologist.[45] In his report, he opined that Johnson suffered from a "severe restrictive lung disease (possibly advanced pulmonary fibrosis)" as the long-term result of inhalation of MBTC and HCl.[46] Dr. Grodzin gave only scattered references to causation in his report, mentioning a study in which rats were exposed to MBTC for six hours a day, five days a week over a four week period.[47] At the end of the study, the rats demonstrated lung inflammation, but as Dr. Grodzin later admitted, that study did not draw any conclusions about the long-term effect of inhalation on the animals, as the animals were sacrificed at the end of the study.[48] Dr. Grodzin also referenced the Material Safety Data Sheet ("MSDS") provided by Arkema for its Certincoat product, which states only that inhalation of Certincoat may cause "respiratory irritation."[49]

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42 *Id.*

43 Ex. J at 130-132.

44 Ex. I at 7-8, 10. Dr. Schlesinger's report stated that Johnson "perhaps" was exposed to vapors of other organotins in addition to MBTC. *Id.* at 3. At his deposition, however, he admitted that he did not know whether Johnson was exposed to other chemicals. *Id.* at 75.

45 Ex. G at 36.

46 Ex. B at 16. As shown in Arkema's Motion in Limine to Preclude the Opinions and Testimony of Dr. Charles J. Grodzin, M.D., "restrictive lung disease" is an umbrella term which covers multiple disorders, many of which have no relation to chemical inhalation. Dr. Grodzin has recently offered a new opinion, well after the disclosure deadline, and after his deposition, in which he now claims that Johnson ***does*** have pulmonary fibrosis. Dr. Grodzin's about-face, however, does not affect this Motion. Pulmonary fibrosis is one type of restrictive lung disease. Just as there is no scientifically reliable evidence that MBTC and/or HCl cause restrictive lung disease in general, there is similarly no evidence that inhaling those chemicals specifically causes pulmonary fibrosis.

47 Ex. B at 9-10; *see* Ex. G at 240-244; Ex. J at 209-210.

48 Ex. G at 240-244.

49 Ex. G at 245-246. A copy of the Arkema MSDS for MBTC is attached as Exhibit K.

ARGUMENT

I. Standards For Summary Judgment

Summary judgment should be granted if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that a party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c). A disputed material fact is genuine if the evidence is such that a jury could return a verdict for the non-moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The initial burden to demonstrate the absence of a genuine issue concerning any material fact is on the moving party. *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). This burden can be satisfied by pointing out an absence of evidence to support an essential element of the non-moving party's case. *Id.* Upon such a showing, the burden shifts to the non-moving party to establish that there is a genuine issue. *Id.* at 324. "[T]he plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Id.* at 322.

II. Plaintiff's Burden Of Proof Regarding Causation Under Texas Law

Plaintiff alleges he was injured in Waco, Texas. Therefore, Texas law governs the sustainability of his claims. *See Wells v. SmithKline Beecham Corp.*, 601 F.3d 375, 378, n. 5 (5th Cir. 2010). Under Texas law, Plaintiff bears the burden of proving, "to a reasonable degree of medical certainty, based on reasonable medical probability and scientifically reliable evidence," that his injuries were caused by exposure to MBTC and HCl. *Cano v. Everest Minerals Corp.*, 362 F. Supp. 2d 814, 817 (W.D. Tex. 2005) *citing Black v. Food Lion, Inc.*, 171 F.3d 308, 310 (5th Cir. 1999). The quantum of proof required is preponderance of the evidence,

that is, "more probable than not." *Southwest Key Program, Inc. v. Gil-Perez*, 81 S.W.3d 269, 275 (Tex. 2002). The Supreme Court of Texas has held that this standard requires Plaintiff to establish "more than 50% probability that the defendant's wrongful conduct caused the harm or injury." *Wells*, 601 F.3d at 378, n.6 *citing Young v. Mem'l Hermann Hosp. Sys.*, 573 F.3d 233, 235 (5th Cir. 2009) (per curiam) and *Havner*, 953 S.W.2d at 715-717.

Under Texas law, causation in a toxic tort case "has two levels, general and specific, and plaintiff must prove both." *Wells,* 601 F.3d at 377-378. "General causation is whether a substance is capable of causing a particular injury or condition in the general population, while specific causation is whether a substance caused a particular individual's injury." *Havner*, 953 S.W.2d at 714. Plaintiff must prove general causation first, because without that predicate of proof, his tort claims fail. *Wells*, 601 F.3d at 378 *citing Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 351 (5th Cir. 2007).

In *Havner*, the Texas Supreme Court made clear that a plaintiff must present "scientifically reliable" evidence in order to establish causation in toxic tort cases. *Havner*, 953 S.W.2d at 714-715. *Havner* and later cases have given further meaning to the requirement that a plaintiff present scientifically reliable evidence of causation. The *Havner* court recognized that, in many toxic tort cases, direct experimentation cannot be done, and there will be no direct evidence of causation. *Id.* at 715. The court held that, in the absence of direct, scientifically reliable proof of general causation, "claimants may attempt to demonstrate that exposure to the substance at issue ***increases the risk of their particular injury***." *Id.* (emphasis added).

One method of demonstrating an increased risk is through epidemiological studies, which examine existing populations to determine if there is an association between a disease or

condition and a suspected causal factor. *Id.*[50] The Fifth Circuit has stated that, in toxic tort cases, epidemiological studies are "the most useful and conclusive type of evidence . . ." *Cano,* 362 F. Supp. 2d at 820 *citing Brock v. Merrell Dow Pharms., Inc.,* 874 F.2d 307, 311 (5th Cir. 1987) *modified by* 884 F.2d 166 (5th Cir. 1989); *see also Castellow v. Chevron USA,* 97 F. Supp. 2d 780, 786 (S.D. Tex. 2000) (epidemiological studies are the "most informative" evidence of a link between a particular chemical and a disease). In fact, the Fifth Circuit has expressly disapproved of "causative conclusions bereft of statistically significant epidemiological support." *Wells,* 601 F.3d at 380; *see also Havner,* 953 S.W. 2d at 727 ("Particularly where, as here, direct experimentation has not been conducted, it is important that any conclusions about causation be reached only after an association is observed in studies among different groups and that the association continues to hold when the effects of other variables are taken into account.")

While certain epidemiological studies may constitute "scientifically reliable" evidence of causation, the court in *Havner* expressly held "[i]solated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered." *Havner,* 953 S.W.2d at 720. This type of evidence is never considered to be "scientifically reliable" proof of causation in toxic tort cases. *Id.*

Finally, if there are other plausible causes of the injury or condition, the plaintiff must offer evidence excluding those causes with reasonable certainty. *Id. citing E.I. du Pont de Nemours & Co. v. Robinson*, 923 S.W.2d 549, 559 (Tex. 1995) (finding that the failure of the expert to rule out other causes of the damage rendered his opinion little more than speculation); *Parker v. Employers Mut. Liab. Ins. Co.*, 440 S.W.2d 43, 47 (Tex. 1969) (holding that a cause

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[50] While *Havner* and other cases have discussed at length the specific requirements that must be met in order for epidemiological studies to be "scientifically reliable" evidence of causation, discussion of those factors is unnecessary here because Plaintiff's experts admit there is ***no*** epidemiological evidence to support their claims. *See, e.g.*, Ex. J at 195-196.

becomes "probable" only when "in the absence of other reasonable causal explanations it becomes more likely than not that the injury was a result").

III. Arkema Is Entitled To Summary Judgment Because There Is No Scientifically Reliable Evidence Of Causation

A. There Is No Scientifically Reliable Evidence That Inhaling MBTC Or HCl Increases The Risk Of Developing A Restrictive Lung Disease

As is common in cases like this, there is no direct evidence, *i.e.*, a controlled scientific experiment, indicating that MBTC or HCl causes restrictive lung disease. Therefore, Plaintiff only can establish general causation by showing, through scientifically reliable evidence, that it is more likely than not that exposure to MBTC and HCl ***increased his risk*** of developing restrictive lung disease. *Havner,* 953 S.W.2d at 715. No such evidence exists.

First, Plaintiff's experts conceded that ***no epidemiological studies*** exist which show that there is any connection between MBTC and/or HCl and Plaintiff's claimed illness.[51] The absence of any epidemiological evidence – the "most useful and conclusive form of evidence" – wholly undermines Plaintiff's claims. *See, e.g., Wells,* 601 F.3d at 380 (disapproving "causative conclusions bereft of statistically significant epidemiological support"). Indeed, Texas courts routinely grant summary judgment in toxic tort cases where the Plaintiff lacks a reliable epidemiological study. *See, e.g. Wells, supra; Cotroneo v. Shaw Envtl. & Infrastructure, Inc.*, 2007 WL 3145791 (S.D. Tex. Oct. 25, 2007).

Not only are there no epidemiological studies showing a connection between MBTC and/or HCl and restrictive lung disease, there no studies of ***any kind*** which show a statistically significant link between MBTC and/or HCl and a restrictive lung disease.[52] No studies have been performed using a scientific method to determine whether there is a "cause and effect"

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51 Ex. G at 239; Ex. J at 195-196.

52 Ex. J at 197-198.

relationship between MBTC and/or HCl and a restrictive lung disease.[53] In fact, as Dr. Schlesinger conceded, there is ***no*** data at all regarding the effect on humans of inhaling MBTC, and "***no data to allow [him] to make any opinion as to whether MBTC specifically will result in chronic lung disease of any kind.***"[54] The only HCl inhalation study performed on humans found no adverse effect on the pulmonary function of asthmatic subjects who were exposed to 1.8 ppm of HCl.[55]

Second, there is no evidence suggesting that exposure to MBTC and HCl increases the risk of contracting a restrictive lung disease. Dr. Schlesinger conceded this fact, and admitted that he could not quantify, in any way, whether exposure to these chemicals increased Plaintiff's risk of developing a lung restriction.[56] Indeed, Dr. Schlesinger ***"drew no conclusions in terms of risk."***[57] Texas law, however, ***requires*** that a Plaintiff produce evidence at least that the substance at issue "substantially elevates" the risk of contracting Plaintiff's alleged disease. *See Havner*, 953 S.W.2d at 717-718 (finding a rational basis to relate the "more likely than not" burden of proof with a requirement that Plaintiff produce evidence of "more than a 'doubling of the risk'"); *Cotroneo,* 2007 WL 3145791, at *3 ("*Havner* may be read to require a relative risk that is only 'substantially elevated' rather than 'doubled'"). Therefore, although Dr. Schlesinger testified that he reviewed the Texas legal standard for causation before arriving at his opinion, he failed to meet it.

Third, there is not even one case report of inhalation of HCl or MBTC causing a restrictive lung disease.[58] Moreover, Owens' safety employees testified that they were unaware

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53 Ex. J at 205-206.
54 Ex. J at 208 (emphasis added).
55 Ex. J at 195, 218-219.
56 Ex. J at 198-199, 204-205, 284-285.
57 Ex. J at 204-205 (emphasis added).
58 Ex. J at 209, 226.

of any other reported instances of a worker developing a chronic restrictive lung disease from inhaling MBTC or HCl.[59] In fact, in an evaluation that was performed at Owens' plant in Lapel, Indiana, the National Institute for Occupational Safety and Health ("NIOSH") reported that, while workers were being exposed to MBTC in excess of the recommended occupational exposure limits, no adverse pulmonary effects were reported.[60]

Finally, the very few documents located by Plaintiff's experts that relate specifically to MBTC or HCl and pulmonary function are in no way "scientifically reliable" evidence of causation. Dr. Schlesinger identified an animal study as showing a "link" between HCl inhalation and pulmonary fibrosis (a restrictive lung disease). On closer examination, however, Dr. Schlesinger conceded that, in the study, only one baboon developed pulmonary fibrosis after being exposed to ***10,000 ppm*** of the chemical for five minutes.[61] By contrast, Johnson's ***peak*** exposure to HCl, assuming Plaintiff's experts are correct, ranged from 10-50 ppm.[62]

Dr. Schlesinger did not attempt to correlate the massive exposure in this study to Johnson's claimed exposure.[63] In fact, Dr. Schlesinger did nothing at all to correlate that study to Plaintiff's claimed exposure.[64] He admitted that it is impossible to draw any conclusion from this study about the relative risk to humans of developing a restrictive lung disease from inhaling HCl.[65] Without any correlation between the animal study and Johnson's alleged exposures, the study fails to qualify as "scientifically reliable" evidence under Texas law. *See, e.g., Havner*, 953 S.W.2d at 729 (rejecting reliance on animal studies where expert did not explain how dosage could be extrapolated to human exposure); *Cotroneo*, 2007 WL 3145791, at *5 (rejecting

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59 Arkema will supplement the record when it receives the transcripts of the recent depositions of Owens employees.

60 Ex. J at 199-204.

61 Ex. J at 230-232.

62 Ex. I at 3.

63 Ex. J at 220-222.

64 Ex. J at 223-224.

65 Ex. J at 208, 219, 223-224.

reliance on animal study where expert did not compare the doses involved in the studies to plaintiff's exposure); *see also Brock,* 874 F.2d at 313 (discussing the "very limited usefulness of animal studies when confronted with issues of toxicity.")

Dr. Schlesinger and Dr. Grodzin also claimed to rely on an animal study in which rodents were exposed to MBTC for six hours a day, five days a week, over a four-week period.[66] As Dr. Grodzin conceded, however, this study drew no conclusions about the long-term effects of exposure to MBTC because the animals were sacrificed shortly after the exposure ceased.[67] Moreover, Dr. Grodzin made no effort to correlate the levels of exposure in the animal studies to Johnson's alleged exposure levels.[68] Indeed, Dr. Schlesinger admitted that Johnson's "exposure scenario" was "different" from the animals in this study.[69] As with the HCl animal study, the MBTC rodent study is not "scientifically reliable" evidence. *See, e.g., Havner*, 953 S.W.2d at 729; *Cotroneo,* 2007 WL 3145791, at * 5.

Dr. Schlesinger also cited to published guidelines regarding occupational exposure levels of MBTC and HCl.[70] The plain language of these documents, however, shows that they offer no reliable support to Plaintiff. Dr. Schlesinger cited to a guideline known as a "TLV" as evidence that Plaintiff was exposed to a dangerous level of MBTC. As Dr. Schlesinger admitted, however, this guideline relates to "Organotins", a family of chemicals which includes MBTC. There are no specific exposure guidelines for MBTC because there is no data on MBTC to support any guidelines.[71] Moreover, these guidelines for "Organotins" were set to regulate exposure to other tin compounds within that chemical family which are much more toxic than

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66 Ex. B at 9; Ex. G at 242-43; Ex. J at 209-210.
67 Ex. G at 242.
68 Ex. G at 241.
69 Ex. J at 214.
70 Certain groups, such as the National Academy of Sciences, publish guidelines which predict the effects that may be seen at certain concentrations and duration of exposure to various chemicals.
71 Ex. J at 217-218.

MBTC.[72] Indeed, Dr. Schlesinger admitted that "if they had data for MBTC the TLV would have been ***higher***."[73]

Similarly, the guidelines for HCl cited by Dr. Schlesinger are of no probative value. He relied on an Acute Exposure Guidelines Level ("AEGL") published by the National Academy of Science. The paper explaining how those levels were set, however, shows that the "human data was limited to one study showing no significant effects in asthmatic subjects and to dated anecdotal information."[74] Thus, the very agency which published this guideline expressly stated that due to the lack of human data, and the flaws in animal studies, its "confidence in the [exposure levels] was moderate at best."[75]

The foregoing undisputed facts demonstrate, as a matter of law, that there is no scientifically reliable evidence linking inhalation of MBTC and/or HCl with the development of restrictive lung disease. Numerous Texas toxic tort cases have rejected attempts to prove causation without scientifically reliable evidence. For example, in *Wells,* the Fifth Circuit affirmed a grant of summary judgment (by excluding plaintiff's causation experts on the same grounds) against a plaintiff who claimed that Requip, a drug for Parkinson's disease, caused his compulsive gambling. In that case, the experts had relied upon: 1) published articles documenting case-specific correlations between Requip and gambling; 2) an unpublished epidemiology study showing a statistically significant link between gambling and the "class" of drugs including Requip; 3) the drug maker's internal data revealing case-specific associations between Requip and gambling; and 4) the fact that the drug maker had changed its warning label to warn of possible gambling side effects. *Wells*, 601 F.3d at 378. The Fifth Circuit held that

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72 Ex. J at 214-218 (emphasis added).
73 Ex. J at 216-218.
74 Schlesinger Deposition Exhibit 7, a copy of which is attached as Exhibit L, at 107.
75 Ex. L at 109.

none of this evidence, which surpasses anything produced by Johnson's experts here, was scientifically reliable. *Id.* at 380-381.

In *Havner,* the Texas Supreme Court reversed a jury verdict for plaintiffs who claimed that Bendectin caused their minor child to be born with a deformed limb. In that case, the plaintiff's expert relied on: 1) epidemiological studies; 2) *in vivo* animal studies; 3) *in vitro* animal studies; and 4) a chemical structure analysis of the main component of Bendectin. *Havner*, 953 S.W.2d at 724. In rejecting this evidence, the court held, among other things, that the epidemiological studies were not statistically significant, and that there was no explanation of how the high dosages in the animal studies could be correlated to human exposure. *Id.* at 725, 729; *see also Burleson v. Tex. Dept. of Crim. Justice,* 393 F.3d 577, 586 (5th Cir. 2004) (affirming grant of summary judgment where plaintiff offered "no epidemiological studies supporting a correlation between the suggested causative agent and the type of cancer experienced by the plaintiff"); *Cotroneo,* 2007 WL 3145791, at *4 (granting summary judgment where it was "undisputed that plaintiffs do not have evidence that plaintiffs' radiation exposure put them at twice the risk (or even a substantially elevated risk) of developing their injuries than the general population).

B. Dr. Schlesinger's General Conclusions Do Not Constitute Reliable Scientific Evidence

In the absence of scientifically reliable evidence connecting Plaintiff's alleged illness with MBTC and/or HCl, Dr. Schlesinger resorted to a shell game based on broad generalizations. He opined that inhalation of respiratory irritants in general "can [] be associated" with "respiratory impairment," depending on the highly individualized response.[76] His broad and conclusory opinions are woefully insufficient to meet Plaintiff's burden of proof.

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[76] Ex. I at 4, 10.

First, Texas courts have rejected attempts to prove causation in toxic tort cases by reference to a toxicological class. *See, e.g., Wells,* 601 F.3d at 380 (rejecting reliance on an epidemiological study which found a statistically significant "class association" between dopamine agonists, the class which included Requip, and impulsive behavior); *Knight v. Kirby Inland Marine Inc.,* 482 F.3d 347, 353 (5th Cir. 2007) (affirming rejection of "a study which focused on organic solvents as a class, including a wide range of chemicals to which [plaintiffs] were never exposed").

It is particularly inappropriate to draw class-based conclusions in this case, because as Dr. Schlesinger admitted, chemicals within the class of respiratory irritants have differing toxicities in the lungs.[77] Thus, different chemicals within the irritant class can cause greater or lesser tissue damage in the lungs than other chemicals within that same class.[78] One reason for this difference is that the chemicals which comprise this class vary in solubility, which affects how far the chemicals will penetrate into the lungs and respiratory tract.[79] In fact, one of the very sources upon which Dr. Schlesinger relied in his report, states that "the health effects of an acute exposure to an irritant gas or vapor are dependent upon the physiochemical properties of that particular gas or vapor, as well as specific host factors."[80] Moreover, the AEGL paper on which Dr. Schlesinger relies notes that "substantial differences" exist in the "toxicological properties" between HCl and hydrogen halides, which are within the same chemical class.[81]

In addition, although Dr. Schlesinger claimed that each chemical within the class will cause inflammation upon inhalation, he admitted that inflammation often resolves on its own,

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77 Ex. J at 188-189.
78 Ex. J at 189.
79 Ex. J at 150-151, 154.
80 Ex. J at 166-167; Schlesinger Deposition Ex. 6, a copy of which is attached as Exhibit M, at 226.
81 Ex. M at 95.

and does not always progress into a chronic condition.[82] Dr. Schlesinger also admitted at his deposition that "the factors that govern whether an initial acute exposure injury progresses to chronic disease are not well defined."[83] Put another way, it is not well-known in the toxicology field why, in some instances, acute exposure will lead to inflammation in some instances that resolves on its own, but in other instances, it will lead to chronic disease.[84] Moreover, only some chemicals within the irritant class are associated with the development of fibrosis.[85]

Second, Dr. Schlesinger's generalizations are particularly unreliable because there is no scientifically reliable evidence to show with reasonable probability that inhalation of chemicals within the class of respiratory irritants leads to restrictive lung disease. There are no epidemiological studies to support Dr. Schlesinger's class-wide conclusions, nor are there any studies showing a statistically significant link between the chemical class of irritants and restrictive lung disease.[86] Lacking this requisite evidence, Dr. Schlesinger opined only that inhalation of respiratory irritants "can be associated" with the development of lung restriction. The Texas Supreme Court has made clear, however, that "testimony to the effect that a substance 'could' or 'can' cause a disease or disorder is not evidence that in reasonable probability it does." *Havner,* 953 S.W.2d at 729. Thus, even with regard to the class of respiratory irritants as a whole, Dr. Schlesinger has failed to offer any scientifically reliable evidence of causation.[87]

Finally, allowing Plaintiff to proceed based on Dr. Schlesinger's broad, generic assertions, could open the door to a plethora of otherwise-untenable toxic tort claims. It is

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82 Ex. J at 181, 185; *see* Ex. J at 117, 159.

83 Ex. J at 179.

84 Ex. J at 180-181.

85 Ex. J at 186.

86 Ex. J at 234-235, 238.

87 Dr. Schlesinger identified three case reports to support his class-based conclusions, one each indicating that a restrictive lung disease resulted from exposure to chlorine, ammonia and nitric acid. Ex. J at 248. It is well-settled, however, "[i]solated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered." *Havner*, 953 S.W.2d at 720.

undisputed that restrictive lung disease can occur without a known cause. It is also undisputed that the toxicological class of respiratory irritants includes many common chemicals such as ozone, chlorine and ammonia.[88] Allowing this Plaintiff to proceed based on the theory that respiratory irritants "can" lead to restrictive lung disease would set precedent which would allow others who develop restrictive lung disease without an apparent cause to claim that it was caused by the chlorine in their swimming pool, or by ammonia in cleaning products, or by ozone in the atmosphere. The spurious cases that would result from acceptance of Dr. Schlesinger's theory simply reinforce the conclusion that Plaintiff cannot be allowed to proceed further in the complete absence of reliable scientific evidence. *See, e.g. Wells,* 601 F.3d at 380 (rejecting reliance on an otherwise reliable epidemiological study because it focused on a class of drugs, some of which "function[ed] differently" than the drug Plaintiff took).

C. Plaintiff's Experts Failed To Negate Other Plausible Causes

In addition to lacking reliable scientific basis, Dr. Schlesinger's class-wide theory fails because he did not exclude the possibility that there were other respiratory irritants in the atmosphere when Johnson claims to have been exposed.[89] In fact, it is undisputed that Owens uses a product called Kleenmold 170 to lubricate glass molds in its bottling process.[90] Among the decomposition products of Kleenmold 170 are sulfur oxides, which are known respiratory irritants.[91] Dr. Schlesinger admitted that he did nothing to determine whether Johnson was exposed to other respiratory irritants, either at work or at home.[92] In fact, Dr. Schlesinger was not even aware of the use of Kleenmold in the plant.[93] Dr. Schlesinger also failed to account for

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88 Ex. J at 70-72, 143-144.
89 Ex. J at 69-71.
90 Expert Report of Janci C. Lindsay, Ph.D, a copy of which is attached as Exhibit N, at 25.
91 Ex. N at 25.
92 Ex. J at 68-74.
93 Ex. J at 68.

an incident which occurred shortly before Plaintiff's second claimed exposure, in which Plaintiff had difficulty breathing in his swimming pool. Chlorine is among the class of irritants referenced by Dr. Schlesinger.[94]

Dr. Schlesinger's failure to investigate, or rule out, the presence of other respiratory irritants to which Johnson may have been exposed further undermines his attempt to rely on class-based toxicology. *See Havner,* 953 S.W.2d at 720 (if there are other plausible causes of the injury or condition, the plaintiff must offer evidence excluding those causes with reasonable certainty).

IV. Arkema Is Entitled To Summary Judgment Because The Testimony Of Drs. Grodzin and Schlesinger Is Inadmissible

Arkema has separately moved under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), to exclude Dr. Grodzin's medical opinions and Dr. Schlesinger's opinions. Arkema incorporates herein by reference the arguments made in support of those Motions. Because Plaintiff has presented no admissible medical evidence, and no admissible evidence of causation, Arkema is entitled to summary judgment.

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94 Ex. J at 71-74.

CONCLUSION

For all of the foregoing reasons, this Court should grant Defendant ARKEMA Inc.'s Motion for Summary Judgment.

Respectfully submitted,

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CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the foregoing was delivered via electronic filing with the Clerk of Court using the CM/ECF system which will send notification of such filing to the following, on this 15th day of October, 2010 as follows:

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